



**THE SECRETARY OF HEALTH AND HUMAN SERVICES**

**WASHINGTON, D.C. 20201**

October 28, 2021

The Honorable Elizabeth Warren  
United States Senate  
Washington, DC 20510

Dear Senator Warren:

Thank you for your letter regarding your support for including the device identifier (DI) portion of a medical device's Unique Device Identifier (UDI) in Medicare claims forms. In your letter, you urged the Department of Health and Human Services and the Centers for Medicare & Medicaid Services (CMS) to expeditiously take steps to add the DI portion of UDIs in Medicare claims, and asked that the agencies commit to finalizing this change as soon as possible.

While the benefits of UDI adoption in health care are well known, as you noted, for any portion of the UDI to be included in Medicare claims, the American National Standard Institute's Accredited Standards Committee (X12) must first submit formal recommendations on the proposed health care claims transaction standards to the National Committee on Vital and Health Statistics (NCVHS). NCVHS must then, after assessing the recommendations, officially recommend to the Department that it should adopt the standards. Finally, the Department's adoption of new standards would still have to be completed through notice and comment rulemaking. Therefore, there is currently no location in the adopted health care claims transaction standards, version 5010, to collect any portion of the UDI. However, the X12 committee has made recommendations to include collection of the DI for high-risk implantable devices, between willing trading partners, in the next version of the claim transactions standards. As noted in a June 25, 2021, article on the X12 website,<sup>1</sup> "X12 releases a new version of each of its implementation guides annually. The DI portion of a medical device's UDI requirements have been included in X12's published implementation guides since the fall of 2020, including version 007030, 008010, and 008020 (coming soon)."

In sum, the Department will have the opportunity to address this issue after we receive the NCVHS recommendations for the next version of all of the standard transactions.

Thank you again for taking the time to provide us with valuable feedback that the agencies can use to inform our process. I will also provide this response to the co-signers of your letter.

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<sup>1</sup> <https://x12.org/news-and-events/news/new-x12-publications-support-inclusion-device-identifiers>

If you have further thoughts or questions, please have your staff contact the Office of the Assistant Secretary for Legislation at (202) 690-7627.

Sincerely,

A handwritten signature in blue ink, appearing to read "Xavier Becerra", with a stylized, cursive script.

Xavier Becerra

Cc:

Hon. Chuck Grassley  
Hon. Bill Pascrell  
Hon. Brian Fitzpatrick  
Hon. Lloyd Doggett